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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/582,779	07/03/2000	MARKUS POMPEJUS	48715	2744
26474	7590	05/04/2004	EXAMINER	
KEIL & WEINKAUF 1350 CONNECTICUT AVENUE, N.W. WASHINGTON, DC 20036			GUZO, DAVID	
			ART UNIT	PAPER NUMBER
			1636	

DATE MAILED: 05/04/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

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**Office Action Summary**

Application No.

09/582,779

Applicant(s)

POMPEJUS ET AL.

Examiner

David Guzo

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 February 2004.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-17 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **Detailed Action**

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/12/03 has been entered.

The outstanding rejection under 35 USC 112, 1<sup>st</sup> paragraph (written description) rejection is withdrawn as a result of applicants' arguments and a review of the prior art. The prior art teaches several orotidine-5'-phosphate decarboxylase genes from various sources as well as functional motifs and active sites in the enzymes encoded by said genes. The skilled artisan would have had sufficient guidance in the generation of the claimed homologs of SEQ ID NO:1 (i.e. sequences with at least 80% or 90% homology with SEQ ID NO:1, etc.).

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 16-17 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Applicants claim homologs of SEQ ID NO:1 or homologs having 80% homology with SEQ ID NO:1. Since the claims do not recite an

isolated or recombinant homolog and since the homologs can read on naturally occurring homologs, the claims read on products of nature.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3-16 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague in that applicants recite the orotidine-5'-phosphate decarboxylase gene having the sequence SEQ ID NO:1 which is **isolated from microorganisms**. SEQ ID NO:1 is the orotidine-5'-decarboxylase decarboxylase gene from the fungus species *A. gossypii*, not some generic "microorganisms". It is unclear what "microorganisms" are contemplated by applicants? Does the term "microorganisms" mean that SEQ ID NO:1 is naturally present in microorganisms other than *A. gossypii* or that the sequence can be introduced into other microorganisms and subsequently isolated from said microorganisms?

Claims 3, 5, 9 and 14 (and dependent claims) are vague in the recitation of a gene "or its homologs as claimed in claim 1" since claim 1 does not recite homologs. There is therefore no antecedent basis for the term "homologs" in claim 1.

Claim 9 is vague in the recitation of the phrase "90% homology with the **sequences** (emphasis added) SEQ ID NO:1 as claimed in claim 1". Since SEQ ID NO:1 is a single sequence, it is unclear what applicants mean by "sequences SEQ ID

NO:1". Claim 9 is also vague in the recitation of the phrase "microorganism which is deficient in orotidine-5'-phosphate decarboxylase nucleic acid sequence having the sequence SEQ ID NO:1" because this phrase is convoluted and confusing. It is unclear if the microorganism must be deficient in or lack some or all of SEQ ID NO:1 or can be deficient in any orotidine-5'-phosphate decarboxylase gene sequence? Also, it is unclear what exactly is meant by "deficient" in a nucleic acid sequence, i.e. does this mean that the whole sequence must be lacking or some part of the sequence?

Claim 11 is vague in that an article should be placed prior to the noun "vector". Redrafting the claim to recite "...is used as the vector." would be remedial.

Claim 12 is vague in that applicants recite a microorganism deficient in multiple orotidine-5'-phosphate decarboxylase genes. It is unclear if applicants are reciting that there is more than one gene encoding orotidine-5'-phosphate decarboxylase in *A. gossypii* and if so, do all of the genes need to be deficient? Also, it is unclear what "deficient", with regard to the orotidine-5'-phosphate decarboxylase gene, means, i.e. does this mean that the gene is absent or defective or the cell does not contain the same copy number as wild-type, etc.?

Claim 13 is vague in that an article needs to be inserted between "as" and "additional". Redrafting the claim to recite "is inserted as an additional gene" would be remedial.

Claims 14 and 15 are vague in that no criteria are recited for selecting the transformed cells. For example, the claims read on a process for selecting *A. gossypii* cells comprising transforming said cells with SEQ ID NO:1; however, since *A. gossypii*

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cells already contain this sequence, it is unclear how transformed cells would be selected.

No Claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo, Ph.D., whose telephone number is (571) 272-0767. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, Ph.D., can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

David Guzo  
April 30, 2004

  
DAVID GUZO  
PRIMARY EXAMINER